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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/763,578   | 07/28/2001  | Ruth F. Eden         | HT-109US            | 9243             |
| 7590   | 05/13/2005  |                      | EXAMINER            |                  |
| James M Deimen<br>Suite 300<br>320 North Main Street<br>Ann Arbor, MI 48104-1192 |             |                      | NGUYEN, BAO THUY L  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1641                |                  |

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| <b>Office Action Summary</b> | <b>Application No.</b>         | <b>Applicant(s)</b> |  |
|------------------------------|--------------------------------|---------------------|--|
|                              | 09/763,578                     | EDEN, RUTH F.       |  |
|                              | Examiner<br>Bao-Thuy L. Nguyen | Art Unit<br>1641    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 24 February 2005.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-15 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-15 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .



**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 February 2005 has been entered.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 5-6 and 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Shi (US 5,998,184) for reasons of record which are reiterated herein below.

Shi discloses a basket bioreactor comprising a cell propagation device for use alone or in combination with any other bioreactor, wherein said device comprises a culture medium vessel and a perforated basket (e.g. enclosure made of a grid material) positioned in the vessel. The screen defines a cell culture zone within the vessel. The

basket perforations are sized, e.g., from 50 120 meshes, to provide a substantially free flow of media in the directions indicated by the arrows in FIG. 2. The basket may be made from metal, such as stainless steel, or any synthetic resin suitably resistant to the bioreactor environment. Such resins include certain polyolefins, polycarbonates and the like. The basket may contain a cell supporting material to entrap anchorage independent cells and to immobilize anchorage dependent cells (e.g. antibody material). The basket may have one removable top cover. Alternatively, it may be designed with many covers to provide stacked sub-columns, thereby accommodating the combined use of different supporting materials. Shi teaches that the cell supporting material is any material useful to anchor or otherwise immobilize cells cultured in a bioreactor. Representative supporting materials include fibra-cell disks, Cytodex Microcarriers or porous ceramics, sponge, fibers, porous beads, and peptide-coated beads. See column 1, line 60 through column 2, line 16; column 5, line 38 through column 6, line 24. Shi teaches removal of cell from the bioreactor by disconnecting and manually shaking the basket. See column 11, lines 46-51.

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi in view of Kadouri et al (US 5,705,390).

See the discussion of Shi above. Shi differs from the instant invention by failing to specifically teach that the means for agitating the cell basket is an attached rod or string.

Kadouri, however, teaches a bioreactor similar to that of Shi. The reactor of Kadouri comprises a reaction vessel having inlet and outlet ports; a cell basket within the reaction vessel for holding a plurality of cell carriers and having sidewall perforations with dimensions such that the cell carriers cannot pass there through. And circulation means for urging the culture medium through the cell basket. See column 2, lines 44-57. Kadouri teaches that cell basket can be rotated about a longitudinal axis that is attached to the basket. Kadouri teaches that the cell basket is removable from the vessel to facilitate replacement of accessories and cleaning. See column 3, lines 9-14; lines 53-62 and figure 1, part 29 (i.e. a rod) and figure 2, part 39 (i.e. pillars).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the cell basket taught by Shi by attached a rod or string such as taught by Kadouri to facilitate the agitation, shaking, removal of the cell basket because such means for agitation or suspension is well known and conventional in the art as demonstrate by Kadouri.

*Response to Arguments*

6. Applicant's arguments filed 24 February 2005 have been fully considered but they are not persuasive.

Applicant argues that Shi does not teach any means to agitate or suspend and agitate the enclosure, and there is also no suggestion of any rod or string to agitate.

This argument has been fully considered but is not persuasive. Shi specifically teaches that the cell basket is manually and gently shaken (column 11, lines 49-50), therefore, Shi necessarily disclose a means for agitating the enclosure. It is true that Shi does not specifically teach that the means for agitating is a rod or string, however, Kadouri teaches a rod attached to a cell basket similar to the basket of Shi and the instant invention, therefore a modification of Shi to attached a rod to facilitate the removal of the basket from the reactor as well as agitating the cell basket would have been obvious.

*Conclusion*

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Bao-Ttuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
5/11/05